

DECLARATION OF EMERGENCY

Department of Health Board of Pharmacy

Standing Orders for Distribution of Naloxone (LAC 46:LIIL.2541)

The Louisiana Board of Pharmacy is exercising the emergency provisions of the Administrative Procedure Act, specifically at R.S. 49:953.B, to promulgate a new rule authorizing pharmacists to distribute naloxone and other opioid antagonists pursuant to standing orders issued by Louisiana-licensed medical practitioners in lieu of patient-specific prescriptions.

The abuse and addiction to opioids is a global problem that is estimated to affect between 26.4 million and 36 million people worldwide. Of those addicted in the United States, 2.1 million are addicted to prescription drugs and another 517,000 are addicted to heroin, according to estimates from the federal Centers for Disease Control and Prevention (CDC). Deaths in the United States, and Louisiana, related to opioid drug use have been rising since 1999, resulting in more deaths in 2014 than ever before. Data from the coroners and medical examiners in Louisiana reveal 100 deaths in this state in 2011 rising over time to 248 deaths in 2015.

Preliminary data for the first six months of 2016 indicate we are on the same deadly trajectory. Naloxone and other opioid antagonists are prescription drugs that produce rapid and dramatic reversals of life-threatening symptoms of opioid-related drug overdoses. Since time is of the essence in drug overdose cases, it is important the drugs be readily available to whoever might first encounter the overdose patient, be it family, caregivers, or first responders.

Act 370 of the 2016 Louisiana Legislature authorized licensed medical practitioners to issue nonpatient-specific standing orders for the distribution of naloxone and other opioid antagonists, in lieu of patient-specific prescriptions those drug products. The legislation also authorized pharmacists to dispense or distribute naloxone and other opioid antagonists pursuant to those standing orders as provided by rules promulgated by the Board Pharmacy.

The board has determined this Emergency Rule is necessary to prevent imminent peril to the public health, safety, and welfare. The Declaration of Emergency is effective August 10, 2016, and shall remain in effect for the maximum time period allowed under the Administrative Procedure Act or until adoption of the final rule, whichever shall first occur.

Title 46 PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIIL. PharmacistsChapter 25. Prescriptions, Drugs, and Devices

Subchapter D. Prescription Drugs

§2541. Standing Orders for Distribution of Naloxone and Other Opioid Antagonists

A. Given the current public health emergency relative to the misuse and abuse of opioid derivatives, public health officials have strongly recommended the widespread availability of naloxone and other opioid antagonists to addicts and their caregivers as well as first responders in the community.

B. For as long as naloxone and other opioid antagonists remain classified as prescription drugs by the federal Food and Drug Administration, pharmacists must secure a prescription or order from a prescriber with the legal authority to prescribe the drug product in order to dispense or distribute the drug product.

C. The Louisiana Legislature has adopted a number of laws designed to facilitate the distribution and dispensing of naloxone and other opioid antagonists beyond the person who would need the medication on an emergent basis to manage an opioid-related drug overdose, more specifically to first responders as well as caregivers and family and friends of potential patients.

1. Act 253 of the 2014 Legislature authorized prescribers to issue prescriptions for naloxone and other opioid antagonists to first responders, and further, authorized pharmacists to recognize such prescriptions as legitimate orders for the dispensing and distribution of naloxone and other opioid antagonist drug products, and further, authorized first responders to have and hold those drug products ready for administration in emergent conditions to manage opioid-related drug overdoses.

2. Act 192 of the 2015 Legislature authorized medical practitioners to prescribe naloxone or another opioid antagonist without having previously examined the individual to whom the medication would be administered, but only under certain conditions specified in the legislation, including the requirement for the prescriber to provide the recipient of the drug with all training and education required for the safe and proper administration of the drug product.

3. Act 370 of the 2016 Legislature authorized medical practitioners to issue nonpatient-specific standing orders to pharmacists authorizing the distribution of naloxone and other opioid antagonists to anyone who might be in a position to assist a patient in the emergent management of an opioid-related drug overdose, but only in compliance with these rules.

a. A nonpatient-specific standing order for the facilitated distribution of naloxone or other opioid antagonist issued by a medical practitioner licensed by the State of Louisiana shall expire one year after the date of issuance.

b. A Louisiana-licensed pharmacist may distribute naloxone or other opioid antagonist according to the terms of the nonpatient-specific standing order issued by a Louisiana-licensed medical practitioner until the expiration date of the standing order. No pharmacist shall distribute naloxone or other opioid antagonist pursuant to a standing order more than one year after the date of issuance of the standing order.

c. Before releasing the naloxone or other opioid antagonist drug product to the recipient, the pharmacist shall verify the recipient's knowledge and understanding of the proper use of the drug product, including, at a minimum:

i. techniques on how to recognize signs of an opioid-related drug overdose;

ii. standards and procedures for the storage and administration of the drug product; and

iii. emergency follow-up procedure including the requirement to summon emergency services either immediately before or immediately after administering the drug product to the individual experiencing the overdose.

d. To comply with the recordkeeping requirements found elsewhere in the board's rules, the pharmacist shall attach a copy of the standing order to the invoice or other record of sale or distribution, and further, shall store these

transaction documents with the other distribution records in the pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 42:

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Executive Director

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